

Food and Drug Administration, HHS

§ 520.2100

(c)(1) *Specifications*. Each tablet contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(2) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.60 of this chapter.

(4) *Conditions of use in growing chickens and growing turkeys*—(i) *Amount*. 1 tablet in each gallon of drinking water (0.002 percent roxarsone).

(ii) *Indications for use*. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) *Limitations*. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[46 FR 41040, Aug. 14, 1981, as amended at 46 FR 42448, Aug. 21, 1981; 47 FR 15238, Apr. 9, 1982; 55 FR 8460, Mar. 8, 1990; 57 FR 8577, Mar. 11, 1992; 58 FR 65664, Dec. 16, 1993; 65 FR 10705, Feb. 29, 2000]

§ 520.2089 Roxarsone liquid.

(a) *Specifications*. Each teaspoon (5 milliliters) of solution contains 72 milligrams of roxarsone (3-nitro-4-hydroxyphenylarsonic acid).

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.60 of this chapter.

(d) *Conditions of use in growing chickens and growing turkeys*—(1) *Amount*. 1 teaspoon (5 milliliters) to each gallon of drinking water (0.002 percent roxarsone).

(2) *Indications for use*. For improved rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) *Limitations*. Administer continuously throughout growing period. Do not administer to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. Use as sole source of organic arsenic. Overdosage or the lack of water intake may result in weakness or paralysis of legs.

[58 FR 65665, Dec. 16, 1993, as amended at 65 FR 10705, Feb. 29, 2000]

§ 520.2098 Selegiline hydrochloride tablets.

(a) *Specifications*. Each tablet contains either 2, 5, 10, 15, or 30 milligrams of selegiline hydrochloride.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs*—(1) *Dosage*. 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(i) *Indications for use*. For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism in dogs.

(ii) *Limitations*. Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dosage*. 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use*. For the control of clinical signs associated with canine cognitive dysfunction syndrome.

(ii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 34632, June 27, 1997; 62 FR 55159, Oct. 23, 1997, as amended at 63 FR 29551, June 1, 1998; 64 FR 2122, Jan. 13, 1999]

§ 520.2100 Selenium, vitamin E capsules.

(a) *Specifications*. The capsules contain 2.19 milligrams of sodium selenite (equivalent to 1 milligram of selenium) and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium) and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate.)

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.

(2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule

§ 520.2122

per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

§ 520.2122 Spectinomycin dihydrochloride oral solution.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. The drug is packaged as an aqueous solution containing 50 milligrams of spectinomycin activity per milliliter.

(b) *Sponsors.* (1) See No. 059130 in § 510.600(c) of this chapter.

(2) See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(2) It is administered orally at the rate of 50 milligrams per 10 pounds body weight twice daily for 3 to 5 days.

(3) Do not administer to pigs over 15 pounds body weight or over 4 weeks of

21 CFR Ch. I (4–1–02 Edition)

age. Do not administer within 21 days of slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 56798, Aug. 26, 1980; 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996; 65 FR 45877, July 26, 2000]

§ 520.2123 Spectinomycin dihydrochloride pentahydrate oral dosage forms.

§ 520.2123a Spectinomycin dihydrochloride pentahydrate tablets.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of spectinomycin cited in this section refer to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs in the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(2) The drug is administered orally to provide 10 milligrams per pound of body weight twice daily. The tablets may be placed in the animal's mouth or crushed and administered in milk or in the feed. Dosage may be continued for 4 consecutive days. Should no improvement be observed, discontinue drug and redetermine diagnosis.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001]

§ 520.2123b Spectinomycin dihydrochloride pentahydrate soluble powder.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means.

(b) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.